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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/634,363	08/09/2000	Kevin Pang	CIBT-P02-058	5665

28120 7590 03/24/2003

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/634,363	Applicant(s) PANG ET AL.	
	Examiner Regina M. DeBerry	Art Unit 1647	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *8-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Status of Application, Amendments and/or Claims

The information disclosure statement filed 05 March 2001 (Paper No. 4) was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Applicant's election with traverse of Group I (claims 1-7) and SEQ ID NO:1 (now SEQ ID NO:2, please below) in Paper No. 12 (06 August 2002) is acknowledged. The traversal is on the grounds that claim 1-12 encompass overlapping subject matter based on methods for contacting pancreatic cells, therefore Groups I-III can be examined simultaneously without significant additional burden. Applicant states that claims 1-6 are linking claims for Groups I-III and that in accordance with MPEP 809, should any linking claim be allowed, the restriction must be withdrawn.

Applicant's arguments have been fully considered but not deemed persuasive for the following reasons. Groups I-III are drawn to methods which require contacting pancreatic tissue with structurally distinct products. In addition claims 1-6 do not constitute linking claims. Please MPEP 809.03 for the definition of linking claims.

The requirement is still deemed proper and is therefore made FINAL. Claims 8-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

The amendment filed 25 November 2002 (Paper No. 14) has been entered in full.

Matter of Record

It is noted that elected SEQ ID NO:1 has been changed to SEQ ID NO:2. The Examiner assumes that the change was due to a mistake in the original claims which incorrectly recited the PYY polynucleotide (SEQ ID NO:1) instead of the PYY polypeptide (SEQ ID NO:2).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a method for promoting the growth of pancreatic cells comprising contacting pancreatic cells with a composition including peptide YY (PYY) or agonist thereof and a method for reducing degeneration of pancreatic tissue comprising contacting the tissue with a composition including peptide YY (PYY) or an agonist thereof.

The instant claims are not supported by an enabling disclosure. The specification fails to teach a method for promoting growth of pancreatic cells or reducing degeneration of pancreatic tissue by contacting the tissue with PYY. The specification

only teaches methods for increasing glucose-responsiveness of pancreatic cells by contacting the cells with PYY. The specification cites art which describes some biological functions of PYY (specification, page 22). The specification, however, does not teach that PYY has the biological function of promoting growth or reducing degeneration of pancreatic tissue. The specification does not disclose working examples demonstrating that PYY can promote growth or reduce degeneration of pancreatic tissue. The specification fails to teach a biological assay (readout) to discern if PYY promoted growth or reduced degeneration of pancreatic tissue.

In addition, the specification fails to teach that any PYY agonist can promote growth or reduce degeneration pancreatic tissue. The specification has not demonstrated that the PYY agonist will bind the PYY receptor and have the same biological function as PYY in pancreatic tissue. Thus the specification has not demonstrated that PYY agonist is really an agonist.

Lastly, the specification fails to teach how to make PYY fragments or PYY agonists that would maintain the activity of promoting growth and reducing degeneration of pancreatic cells. PYY agonists can encompass mutated sequences or allelic variants. However, the instant claims fail to recite any sequence limitations, and thus the skilled artisan would have to resort to trial and error experimentation to identify sequences meeting the functional limitations of the claims. At the time of the invention, the state of the art established that mutation of naturally occurring sequences was more likely than not to result in loss of biological activity. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's

sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, catalysis and in providing the correct three-dimensional spatial orientation of binding and catalytic sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions. See Wells *et al.*

Due to the large quantity of experimentation necessary to demonstrate that PYY and PYY agonist can promote growth and reduce degeneration in pancreatic tissue, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which does not teach that PYY has the biological functions of promoting growth and reducing degeneration in pancreatic cells, and the breadth of the claims which fail to recite sequence limitations regarding PYY agonists, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification provides adequate written description for PYY but not PYY fragments or PYY agonists. The instant claims are directed to methods comprising

contacting pancreatic tissues with PYY or an agonist or fragment thereof. The instant claims are directed to encompass any PYY fragment or PYY agonist. This could include compounds, gene sequences, corresponding sequences from other species, mutated sequences, allelic variants, splice variants and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of PYY the skilled artisan cannot envision the detailed chemical structure of a PYY agonist (polynucleotides and/or proteins), regardless of the complexity or simplicity of the method of isolation. None of these sequences meet the written description provision of 35 USC 112, first paragraph. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only PYY but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Bertrand *et al.*, Pancreas 7(5):595-600, 1992, abstract. The instant claims are drawn to a method for promoting the growth of pancreatic cells comprising contacting pancreatic cells with a composition including peptide YY (PYY) or an agonist thereof and a method for reducing degeneration of pancreatic tissue comprising contacting the tissue with a composition including peptide YY (PYY) or an agonist thereof.

Bertrand teaches the effects of adding PYY to isolated rat pancreas. "Promoting the growth of pancreatic cells" and "reducing degeneration of pancreatic tissue" are the

intended uses recited in the instant claims and are not given significant patentable weight. Bertrand's teachings of the inhibitory effect of PYY on insulin secretion does not teach against the intended use cited in the claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

RMD
March 11, 2003